

Remarks

Non-statutory Subject Matter Claim Rejection

Claims 2 and 3 stand rejected under 35 U.S.C. §101 as being non-statutory. Claims 2 and 3 depend from claim 1, which has not been rejected under 35 U.S.C. §101. Clearly, if claim 1 is statutory and claims 2 and 3 claim further structural elements, as they do, they cannot, by definition (37 C.F.R. § 1.75(c)), be non-statutory under 35 U.S.C. §101. This rejection under § 101 is not well taken and should be withdrawn.

Rejection under 35 U.S.C. §102

Claims 1-7 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. 6,602,182, to Milbocker. That rejection is respectfully traversed. In short, Milbocker does not remotely anticipate claims 1-7.

It is, well known, that an anticipation rejection is narrow, and easily overcome because the allegedly anticipating references must teach every aspect of the claimed invention MPEP 706.021V.

In the first instance it is to be noted that the present invention has a “controller means” element, claim 1, as follows:

...controller means, the controller means being adapted to actuate the pump means and the pressure regulator means so that fluid is pumped substantially continuously by the pump means to the input port and the pressure regulator means intermittently inflates and deflates the chambers starting at the apex of the heart to create a rhythmic massage of the heart from its apex to its base thereby substantially imitating the natural contraction of the heart, the controller means being further adapted to receive sensor information input from...

It is, of course, significant to the present invention that a “controller means and the regulator means inflate and deflate the chambers “to create a rhythmic massage of the heart from its apex to its base thereby substantially imitating the natural contraction of the heart...”

Even a cursory review of the device of Milbocker indicates that it does not and could not possibly operate and have the structure required by the present invention “to create a rhythmic massage of the heart from its apex to its base...” For example, FIG. 16 is said to be a schematic diagram of a united system for cardiac assistance according to the invention.

Clearly, the device of FIG. 16 feeds fluid from the base of the heart towards its apex. It could not, therefore, “imitate the natural contraction of the heart” as is required by applicants’ claim 1 since a heart contracts naturally apex to base.

In fact, the Milbocker device works in exactly the opposite fashion as the present device and would, in fact, be working against the natural contraction of the heart from its apex to its base. It would, in fact, conflict with a heart were the heart to have any underlying cardiac rhythm. Clearly therefore, claims 1-6 are not anticipated by anything proposed in the Milbocker ‘182 patent. There are numerous other bases upon which Milbocker does not anticipate claims 1-6, which do not require further discussion.

There are further bases upon which it is abundantly obvious that the Milbocker ‘182 patent does not anticipate the present invention. For example, Milbocker is described, “to sense the heart’s electrical signals and synchronize pump activation.” No mechanism is described for stimulating the heart muscle to contract on its own. An important and frequent component of heart failure is that the normal electrical dispersion through the heart muscle is disturbed thereby making the contraction of the heart less efficient. The heart muscle is not stimulated in its normal optimum pathway. It also disturbs the valvular function of the heart thereby further aggravating the heart failure. The Milbocker device in no way addresses this aspect of heart failure and certainly does not anticipate apparatus claims 1-6 and especially method claim 7.

It is important to reference the activity of the heart muscle itself in this situation i.e., where a device causes the heart to contract when there is active muscular contraction. This is referred to as an active device. The present device provides for phased array or a coordinated electrical stimulation of the heart to restore its normal contract sequence bringing about a normalization of the active phase of contradiction. An external device applied to the heart muscle, which does not cause intrinsic contraction of the muscle, is referred to as passive contraction in reference again to the activity of the heart muscle. The Milbocker device is a passive ventricular assist device in that it does not stimulate heart muscle activity but merely applies a pressure to the outside of the heart. Again, Milbocker does not and could not anticipate the presently pending claims.

Section 112 Rejections

Claim 1 stand rejected as being indefinite under 35 U.S.C. §112. Claim 1 has been amended to overcome this rejection by correcting a clerical error.

Claims 3 and 4 have been amended to overcome the Examiner's stylistic objection of the last paragraph of this Office Action.

Claim 5 has been amended to conform it to the specification.

Claim 7 has been amended to conform the claim to the disclosure.

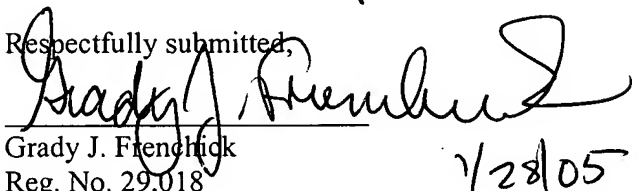
New Claim 8

Claim 8 has been added to specifically claim Bourden tubes described at page 10, line 18 of the disclosure. No new matter has been added.

Conclusion

It is believed that all claims are now in condition for allowance. An early notice of same is earnestly solicited.

Respectfully submitted,


Grady J. Frenchick
Reg. No. 29,018

1/28/05

File No. 021587-9001-02
Michael Best & Friedrich LLP
One South Pinckney Street
P. O. Box 1806
Madison, WI 53701-1806
(608) 257-3501
Q:\CLIENT\021587\9001\B0386721.1